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CONTRACTING ORGANIZATION:

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for the Advancement of Military Medicine

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14. ABSTRACT
In *Project 1*, we are adapting and empirically evaluating a safety plan intervention targeted at suicidal military service members receiving care at the Walter Reed National Military Medical Center. Outcomes include suicide ideation, suicide-related coping, and attitudes toward help seeking at discharge, 1-month, and 6-months post discharge. As of 9/24/2014, recruitment and follow-up activities are complete with 102 participants out of the 186 expected enrolled. In *Project 2*, we are examining the effectiveness of a comprehensive intervention including the safety plan intervention and follow-up care, for veterans at high suicide risk at VA Emergency Departments (ED). Outcomes include suicide attempts, suicide ideation, and suicide-related coping at 1, 3, and 6 months following the index ED visit, as well as attendance at an outpatient mental health or substance abuse treatment appointment within 30 days post index ED visit. As of 9/24/2014, recruitment and follow-up activities are complete with 332 participants out of the 600 expected enrolled across sites.

15. SUBJECT TERMS
Suicide Prevention, Safety Planning, Acute Care, Inpatient Treatment

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Introduction

The Army Suicide Event Reporting (ASER) and the Total Army Injury and Health Outcomes Database (TAIHOD) systems have indicated increasing rates of suicide among Active Army, Guard, and Reserve units over the last several years. Additionally, research has indicated that veterans are more than twice as likely to kill themselves as compared to the general population. There are limited evidence-based suicide prevention interventions that have been developed for military personnel and veterans who are experiencing suicide ideation or who have made a suicide attempt. The objective of the research described in this annual report is to adapt and evaluate a brief, readily accessible, and personalized intervention, safety planning, that aims to reduce suicide risk in military and veteran populations in three ways by: (1) evaluating suicide risk using a structured assessment measure; (2) enhancing suicide-related coping strategies; and (3) increasing acceptability and initiation of appropriate mental health and substance use treatments. This research is unique in that the intervention, safety planning, is being evaluated in both military and VA settings, with the aim of disseminating related educational materials to both military and VA patients and providers. The specific aims are to evaluate the efficacy of the safety planning intervention on suicide ideation, suicide-related coping, and attitudes toward help seeking for hospitalized military personnel at *high risk* for suicide and to evaluate the effectiveness of the safety planning intervention on suicide attempts, suicide ideation, attendance of outpatient mental health and substance abuse interventions, and suicide- related coping for veterans at high suicide risk in emergency department (ED) settings. Two separate, but related projects are being conducted to compare the study intervention with enhanced usual care conditions on suicide-related outcomes. In *Project 1*, the safety planning intervention has been adapted for military service members who are at high risk for suicide. A randomized controlled trial is being conducted to determine the efficacy of the safety planning intervention for hospitalized military personnel at the Walter Reed National Military Medical Center (formerly Walter Reed Army Medical Center). Outcomes include suicide ideation, suicide-related coping, and attitudes toward help seeking at discharge, 1-month, and 6-months post discharge. In *Project 2,* a quasi-experimental design is being used to examine the effectiveness of a comprehensive intervention including the safety plan intervention and follow-up care, for veterans at *high risk* for suicide at VA ED. Outcomes include suicide attempts, suicide ideation, and suicide-related coping at 1, 3, and 6 months following the index ED visit as well as attendance at an outpatient mental health or substance abuse treatment appointment within 30 days post the index ED visit. If the safety plan intervention is determined to be effective, then this intervention may be widely and quickly disseminated in the DoD and VA settings through publications and presentations using a variety of multi-media platforms. The ultimate goal of the safety plan dissemination initiative is to provide clinicians and other professionals who work with high risk military service members and veterans with a brief, easily administered intervention that is designed to mitigate suicide risk.

Body

During Year 5 of this project, our team has met all reporting guidelines for 19 regulatory agencies and obtained timely approvals on annual reviews. Recruitment of participants for SAFEMIL has been completed at the Walter Reed National Military Medical Center (WRNMMC) for Project 1 with a total of 102 participants out of the expected 186 (i.e., 55%) recruited. At the time of last year's (Year 4) annual report, recruitment activities were completed at all SAFEVET (Project 2) sites. A total of 332 participants out of the expected 600 (i.e., 55%) were recruited. Follow-ups for study participants in both SAFEMIL and SAFEVET were completed in the past year. The study PIs have been meeting at least once a week to discuss study objectives, methodology, timeline, individual responsibilities, and coordinating manuscript preparation. Discussions are documented in weekly *Meeting Minutes*. Year 5 focused heavily on completing recruitment and follow-up for Project 1, completing follow-up for Project 2, preparation and submission of IRB regulatory-related materials to satisfy Continuing Review or Site Closure requirements as appropriate (both Projects), data analysis, and manuscript preparation. After the completion of follow-up activities on each Project, we focused on cleaning individual site databases and merging all de-identified data from Project 2 into one database. Finally, we have submitted a 6-month no-cost extension request for both projects to allow for continuing data analysis and manuscript preparation. At many study-sites, lengthy initial regulatory review processes delayed the beginning of recruitment and as a result, participant enrollment has been lower than expected. A detailed summary of the progress for each project is detailed below.

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Key Research Accomplishments

For the 5th year reporting period, here is a listing of all activities associated with SAFEMIL and SAFEVET.

Section I – SAFEMIL Progress
Safety Planning for Military (SAFE-MIL) - Walter Reed National Military Medical Center

1. Enrollment and Participant Follow-Up
The SAFEMIL project competed participant recruitment at the end of the first quarter of the current reporting period (December 2013). An additional 9 participants were recruited; overall, 102 participants were enrolled into the study. All participant follow-ups were completed in July 2014. We successfully completed 70 one-month follow-up assessments and 70 six-month assessments.

2. Continuing Review
We submitted our continuing review report to WRNMMC IRB (our lead site) on November 22, 2013 and received approval on December 12, 2013. We subsequently received secondary concurrence from the USUHS IRB and HRPO.

3. Obtained IRB Approval for the Closing of the Fort Belvoir Recruitment Site
At the time of the continuing review in December 2013, we closed the Fort Belvoir recruitment site. The IRB approved the closure on 1/23/2014. We were unable to recruit anyone at this site due to lengthy start up procedures that took more time than anticipated.

4. Data Entry to the SAFEMIL Master Database
Data entry into the master database continued during this reporting period. All data has been entered into the database and has been cleaned.

5. Manuscript Preparation
We submitted a manuscript detailing the methods of the SAFEMIL project to *Contemporary Clinical Trials*. The manuscript is entitled "Safety Planning for Military (SAFE MIL): Rationale, Design, and Safety Considerations of a Randomized Controlled Trial to Reduce Suicide Risk among Psychiatric Inpatients". Dr. Holloway took the lead in writing this paper. In addition, Dr. Holloway collaborated with the other PIs on a manuscript detailing the SAFEVET methods (Lead author: Dr. Currier) which is expected to be submitted soon.

5. Data Analysis
We have begun to analyze the study data and to prepare a manuscript to summarize the RCT findings. During each biweekly call, we review the preliminary data analysis on baseline information and discuss next steps. We have not yet examined the change from the time of baseline to follow-up but expect to move forward with this step once we have best understood the baseline study data.

Section II – SAFEVET Progress
Safety Planning for Veterans (SAFEVET) – VA Emergency Departments

Regulatory Approvals: We obtained either Continuing Review or Site Closure approvals from local IRBs at all study sites during Year 5 of the project. In addition, the Chesapeake IRB provided approval for the entire study in May 2014. Finally, all study sites obtained secondary concurrence from the HRPO since the last Annual Report. The sites that received closure approvals are: Portland VAMC, Long Beach VAMC, and Bronx VAMC. The remaining 6 sites continue to have approval from all IRBs and the HRPO.

Enrollment and Follow-up: Recruitment at all actively recruiting sites was ended at the end of Year 4. Follow-up concluded during the second quarter of the current reporting period. Please see Appendix B for recruitment and follow-up numbers for each site and for the project as a whole.

Activities for Canandaigua VAMC Site:

The Center of Excellence at Canandaigua has functioned as the principal coordinating site for the SAFE VET clinical demonstration project, which served as the basis for the VA-based portion of the project: A Brief Intervention to Reduce Suicide Risk in Military Service Members and Veterans. Grant-related activities for the period 9/25/13 through 9/24/14 included:

1. Participated in weekly PI conference calls.
2. Worked with PI group to clean project data and initiated statistical analyses of SAFE VET CDP component.
3. Worked with Portland and San Diego sites to manage questions and discrepancies in study data from those sites.
4. Presented SAFE VET/SAFE MIL progress updates at VISN-2 COE Advisory and Executive Boards.
5. Managed IRB updates and continuing review: Syracuse VAMC.
6. Working with PI group, initiated two manuscripts describing SAFE VET/MIL Design and Methodology. SAFE MIL manuscript has been submitted for publication on 3/21/14 [Holloway, lead author]. SAFE VET Manuscript is under review by PI group.
7. The San Diego site remains open for data analysis only and the Portland VAMC IRB approved the Portland site's closure during Year 5.

Activities at Columbia University Site

For the reporting period from September 24, 2013 to September 24, 2014, here is a listing of all site-specific activities associated with SAFEMIL and SAFEVET at the Columbia University site:

1. Updated IRB Approvals and Renewals
Throughout the reporting period, IRB approval remained active at both the Manhattan VA and Bronx VAMC sites. The Bronx VAMC site received approval from the Bronx VAMC IRB to close their site in April 2014. The Manhattan VA site remains open for data analysis only.

2. Data Collection
Data collection for both the Manhattan and Bronx VA sites is complete. Data has been cleaned and entered into a database along with data from all other SAFEVET sites. The data is currently being analyzed. Specifically, Columbia University is analyzing the suicide-related coping assessment, as well as suicidal ideation and suicidal behavior outcomes.

3. Dissemination of study-related information
Columbia University made substantial progress on the preparation of several manuscripts for publication. These manuscripts include: 1) a description of the SAFEVET intervention with case examples; 2) Veteran response to SAFEVET based on the key informant interviews; 3) clinical staff response on implementation of the SAFEVET intervention based on the key informant interviews; and 4) outcomes with respect to treatment engagement and suicidality.

Activities at the Denver VAMC Site

1. The Denver VA site received Continuing Review approval from their local IRB, Chesapeake IRB and HRPO IRB. They have also received approvals for amendments that were submitted to remain in compliance with changing VA requirements. The Long Beach site continued collaborations with the Denver site in regards to regulatory requirements. The Long Beach site received approval from their local IRB to close their site on 7/3/2014.

2. The Denver site PI continued to participate in control site and/or PI conference calls. The Denver site Study Coordinator and/or Assessor continued to participate in phone calls to facilitate communication and consistency across sites.

3. Regarding assessment, Denver assessors continued to complete assessments for participants previously recruited at the Long Beach site.

4. Throughout year 5, the Denver site continued to collaborate with the Long Beach site behind the VA firewall to facilitate the secure sharing of data

5. The Denver team has developed Data Use Agreements and is facilitating the process of securely receiving study data for analysis and utilization in manuscripts.

6. The Denver team is beginning to work on manuscripts and taking the lead regarding a manuscript regarding validating the C-SSRS among Veterans.

Activities at the Philadelphia VAMC Site

1. Since the beginning of the study, the Philadelphia VAMC site enrolled 62 participants and 29 have completed the study. The Milwaukee VAMC site enrolled 64 participants and 36 have completed the study. These are the final study enrollment and completion numbers.

2. Study assessors at the Philadelphia VAMC site participated in monthly assessor calls with the other study sites.

3. IRB approval for our continuing review was received on January 7, 2014. The Philadelphia VAMC site assisted all sites with completing continuing review and amendment submissions and coordinated sites' continuing review submissions to Chesapeake IRB and the HRPO. We advised sites on local SAE reporting requirements, disseminated local SAE reports to all MOMRP sites, provided guidance to all sites on reporting of external SAEs, and coordinated the submission of SAE reports to Chesapeake IRB and the HRPO as required. We tracked all sites' current IRB due dates and status of sites' continuing reviews and amendment submissions. The next Philadelphia VAMC continuing review submission is due on October 20, 2014.

3. The Philadelphia VAMC site provided guidance and quality control to all assessment sites regarding the assessment database. We helped SAFEMIL staff troubleshoot data entry errors and provided guidance on cleaning data and double data entry.

4. The Philadelphia VAMC site tracked all sites' screening and enrollment, participant follow-up, and adverse events and we created reports which were presented to project PIs on a weekly basis.

5. The Philadelphia VAMC obtained de-identified data from the 4 Intervention sites and 4 Control sites and merged the data into one database. Data analysis of the baseline data is underway, and analysis of follow-up data has begun.

Reportable Outcomes

Peer Reviewed Manuscripts

Ghahramanlou-Holloway, M. (2013). A brief intervention to reduce suicide risk in military service members and Veterans: A case example. In L. Resnik, G. E., Reiber, P. Steager, R. K. Evans, K. Barnabe, & J. Harris (Eds.), *VA/DoD collaboration guidebook for healthcare research*, Department of Veterans Affairs. http://www.research.va.gov/va-dod/

Ghahramanlou-Holloway, M., Brown, G. K., Currier, G. W., Brenner, L., Knox, K. L., Grammer, G., Carreno-Ponce, J. T., & Stanley, B. (2014). Safety Planning for Military (SAFE MIL): Rationale, design, and safety considerations of a randomized controlled trial to reduce suicide risk among psychiatric inpatients. *Contemporary Clinical Trials, 39,* 113-123.

Gharamanlou-Holloway, M., Tucker, J., Neely, L. L., Carreno-Ponce, J. T., Ryan, K., Holloway, K., & George, B. (2014). Suicide risk among military women. *Psychiatric Annals, 44*(4), 189-193.

Ghahramanlou-Holloway, M., Neely, L., & Tucker, J. (in press). Treating suicide risk in inpatient settings. In C. J. Bryan (Ed.), *A guide to brief cognitive behavioral treatments for suicide risk across clinical settings*. New York: Routledge.

Neely, L. L., Tucker, J., Carreno, J. T., Grammer, G., & Ghahramanlou-Holloway, M. (in press). Suicide risk assessment and management guidance for military psychologists. *Military Psychology*.

United States Air Force Medical Operations Agency. (2013). Air Force guide for suicide risk assessment, management, and treatment. San Antonio, Texas.

> (Brigadier General Sean Murphy, Commander, Air Force Medical Operations Agency, "This Suicide Risk Guide was created in collaboration with our Nation's leading suicidologists and is considered as a one-of-a-kind product without equal in the military or civilian community". All MTF MH Clinics must implement the requirements of this Suicide Risk Guide by 1 Feb 2014".

Presentations

Ghahramanlou-Holloway, M. (2014, May). A brief intervention to reduce suicide risk in military service members and Veterans. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Fort Detrick, MD.

Ghahramanlou-Holloway, M. (2014, April). Treatment needs of suicidal military personnel and family members. Invited presentation at 1st Science Roundtable organized by the Military Family Research Institute (MFRI) in partnership with Senator Joe Donnelly's office, Capital Hill, Washington, DC.

Carreno-Ponce, J. T. & Ghahramanlou-Holloway, M. (2013, December). Brief intervention to reduce suicide risk in military service members and Veterans. Invited presentation at the Research DoD/VA Educational Summit, DoD Suicide Prevention Office. Washington, DC.

Ghahramanlou-Holloway, M. (2013, December). Overview of three military suicide prevention studies. Presentation at the Medical and Clinical Psychology Colloquium Series at Uniformed Services University of the Health Sciences, Bethesda, MD.

Safety Plan iTunes App Released
(funded by OMH Suicide Prevention Center of New York, Columbia U)

Safety Planning Online Training http://zerosuicide.actionallianceforsuicideprevention.org/

Conclusion

For SAFEMIL, the fifth year has been focused on completing participant recruitment and follow-up, data entry and data cleaning, and preparing manuscripts to report on study results. Recruitment ended in December 2013 with 102 participants enrolled in the SAFEMIL study. Follow-up was completed in July 2014; 70 participants completed the 1-month follow-up and 71 participants completed the 6-month follow-up. Please see Appendix E for the final Project 1 CONSORT diagram.

Regarding the SAFEVET study, the fifth year focused on obtaining either IRB continuing review approvals or IRB site closure approvals, as appropriate, at all sites, coordinating activities between Assessment sites and their paired Control sites, completing participant follow-up at Control sites, cleaning individual sites' data, merging the data into one de-identified database, beginning to conduct data analysis, and preparing manuscripts for publication. At the end of Year 5, all sites have completed recruitment and follow-up activities. A total of 332 participants were enrolled into the SAFEVET study across all eight sites, and 141 completed the 6-month assessment.

This study represents the only combined efficacy and effectiveness trial addressing the needs of military personnel and veterans following a suicidal crisis. Given the magnitude of the public health problem presented by suicide-related ideation and behaviors in the military, there is a significant need for empirically supported treatments that directly address the needs of this at high-risk individuals.

References

None.

Appendices

Appendix A: IRB Related Progress for SAFEVET and SAFEMIL Projects

Appendix B: SAFEVET Enrollment Report and Adverse Event Log

Appendix C: SAFEMIL Enrollment Report and Adverse Event Log

Appendix D: SAFEVET and SAFEMIL Participants Lost to Follow-up

Appendix E: SAFEMIL CONSORT Diagram, Since Last Annual Report

Appendix F: SAFEMIL Baseline Demographic Data and SAFEMIL Baseline Suicide Attempt Data

APPENDIX A
SAFEVET Enrollment Report (As of September 24, 2014)

IRB	Site #1 Bronx VAMC CONTROL	Site #2 Canandaigua VAMC ASSESSMENT SITE[1]	Site #3 San Diego VAMC CONTROL	Site #4 Denver VAMC SAFEVET	Site #5 Long Beach VAMC CONTROL
Site PI	Leo Sher	Glenn Currier Kerry Knox	Kathleen Kim	Lisa Brenner	Lawrence Albers
VA IRB	Initial Approval 12/2/10 Site closure approved: 6/9/2014	Syracuse IRB Initial Approval 1/3/11 CR Approved: 10/28/13	Initial Approval 3/3/11 CR Approved: 1/21/14	Initial Approval 5/7/10 CR Approved: 1/21/14	Initial Approval 6/9/11 Site closure approved: 1/9/14
PI Institutional IRB	NA	NA	NA	NA	NA
Chesapeake IRB	Initial Approval 5/25/11	Initial Approval 4/5/11	Initial Approval 7/6/2011	Initial Approval 9/09/2010	Initial Approval 8/31/11
HRPO	Initial Approval 6/21/11 HRPO A-15768.h	Initial Approval 5/25/11 HRPO A-15768.f	Initial Approval 6/25/12 HRPO A-15768.i	Initial Approval 9/14/10 HRPO A-15768.a	Initial Approval 9/20/11 HRPO A-15768.j
Other IRB	NA	NA	NA	NA	NA
RISK	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk
SAMPLE SIZE	N = 75 at BVAMC	N = 75 at CVAMC	N = 75 at SDVAMC	N = 75 at DVAMC	N = 75 at LBVAMC

[1] Assessment Center for San Diego and Portland VAMCs

IRB	Site #6 Manhattan VAMC SAFEVET	Site #7 Milwaukee VAMC CONTROL	Site #8 Philadelphia VAMC SAFEVET	Site #9 Portland VAMC SAFEVET	Site #10 WRAMC SAFEMIL
Site PI	Christie Jackson	Bert Berger	Gregory Brown	Lauren Denneson	Marjan Holloway
VA IRB	Initial Approval 5/3/10 CR Approved 2/4/14	Initial Approval 2/15/11 CR Approved 2/3/14	Initial Approval 5/12/10 CR Approved: 12/18/13	Initial Approval 11/3/210 Site closure approved: 4/9/14	NA
PI Institutional IRB	NA	NA	NA	NA	USUHS (SAFEMIL ONLY) Initial Approval 12/22/11
Chesapeake IRB	Initial Approval 6/17/10	Initial Approval 4/5/11	Initial Approval 8/09/10	Initial Approval 1/31/11	NA
HRPO	Initial Approval 9/24/10 HRPO A-15768.b	Initial Approval 5/25/11 HRPO A-15768.g	Initial Approval 9/02/10 HRPO A-15768.c	Initial Approval 2/28/11 HRPO A-15768.d	Initial Approval 2/17/12 HRPO A-15768.e
Other IRB	NA	NA	NA	NA	WRNMMC Initial Approval 12/22/11 CR Approved 2/11/13
RISK	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	Greater than Minimal Risk
SAMPLE SIZE	N = 75	N = 75	N = 75	N = 75	N = 186

CR = Continuing Review; CIC = Clinical Investigations Committee; HRPO = Human Research Protections Office; HUC = Human Use Committee; USUHS = Uniformed Services University of the Health Sciences; VAMC = Veterans Affairs Medical Center; WRAMC = Walter Reed Army Medical Center

APPENDIX B
SAFEVET Enrollment Report and Adverse Event Log (FINAL)

	Assessed for Eligibility	Ineligible	Eligible but Refused Entry into Study	Enrolled	Active	Completed Baseline Assessment	Completed 1-mo follow-up	Completed 3-month follow-up	Completed Study	Lost to Follow-up	# AEs
Total (all sites):	**489**	**105**	**52**	**332**	**0**	**238**	**185**	**154**	**141**	**191**	**11**
Bronx	22	3	3	16	0	11	6	3	7	9	0
Denver	87	9	3	75	0	59	47	41	38	37	2
Long Beach	71	10	14	47	0	26	23	21	14	33	3
Manhattan	95	27	15	53	0	31	16	16	12	41	2
Milwaukee	100	27	9	64	0	56	47	37	36	28	2
Philadelphia	92	25	5	62	0	45	39	31	29	33	1
Portland	20	4	3	13	0	8	6	4	4	9	1
San Diego	2	0	0	2	0	2	1	1	1	1	0

SAFEVET Adverse Events Log (FINAL)

Site	Date of Event	Date Discovered	Date Reported to Local IRB	Related to Study	Expected	Description
Manhattan	2/17/11	2/18/11	2/25/11	No	Yes	Suicide Attempt
Philadelphia	7/13/11	7/29/11	7/29/11	No	No	Hit by Train Resulting in Death
Denver	8/2/11	8/5/11	8/8/11	No	Yes	Suicide Attempt Resulting in Death
Portland	4/26/12	5/24/12	5/29/12	No	Yes	Suicide Attempt
Milwaukee	5/15/12	5/15/12	5/21/12	No	No	Suicidal Ideation/Homicidal Ideation
Manhattan	5/10/12	5/24/12	6/1/12	No	Yes	Suicide Attempt
Long Beach	6/27/12	6/27/12	7/3/12	No	Yes	Suicide Ideation leading to inpatient hospitalization
Long Beach	10/10/12	10/23/12	10/29/12	No	Yes	Lethargy and hypersomnolence leading to involuntary hospitalization
Long Beach	12/29/2012	1/3/2013	1/3/2013	No	Yes	Substance induced psychosis leading to inpatient hospitalization
Milwaukee	2/4/2013	2/5/2013	2/6/2013	No	Yes	Suicide Attempt
Denver	12/18/2012	2/27/2013	3/4/2013	No	Yes	Increased depression and suicidal ideation leading to inpatient hospitalization

APPENDIX C

SAFEMIL Enrollment Report and Adverse Event Log (Final)

	Assessed for Eligibility	Ineligible	Eligible but Refused Entry into Study	Eligible but not Enrolled – Other Reasons	Enrolled	Active	Completed Baseline Assessment	Completed Discharge Assessment	Completed 1-month follow-up	Completed 6-month follow-up	Lost to Follow-up	# AEs
SAFEMIL	352	118	51	81	102	0	102	91	70	71	31	5

SAFEMIL Adverse Events Log (Final)

Date of Event	Date Discovered	Date Reported to Local IRB	Related to Study	Expected/ Unexpected	Description
10/4/2011	10/5/2011	10/5/2011	No	Expected	Suicide Ideation leading to involuntary hospitalization
10/1/2011	11/2/2011	11/2/2011	No	Unexpected	Participant in federal custody
12/3/2011	12/4/2011	12/6/2011	No	Expected	Admitted to inpatient unit for possible suicide ideation, cutting behaviors, and high blood alcohol content.
10/11/2011	11/8/2011	11/9/2011	No	Expected	Depression leading to voluntary psychiatric hospitalization
10/8/2013	10/8/2013	10/9/2013	No	Unexpected	Homicidal Ideation

APPENDIX D

SAFEVET and SAFEMIL Participants Lost to Follow-up (Final)

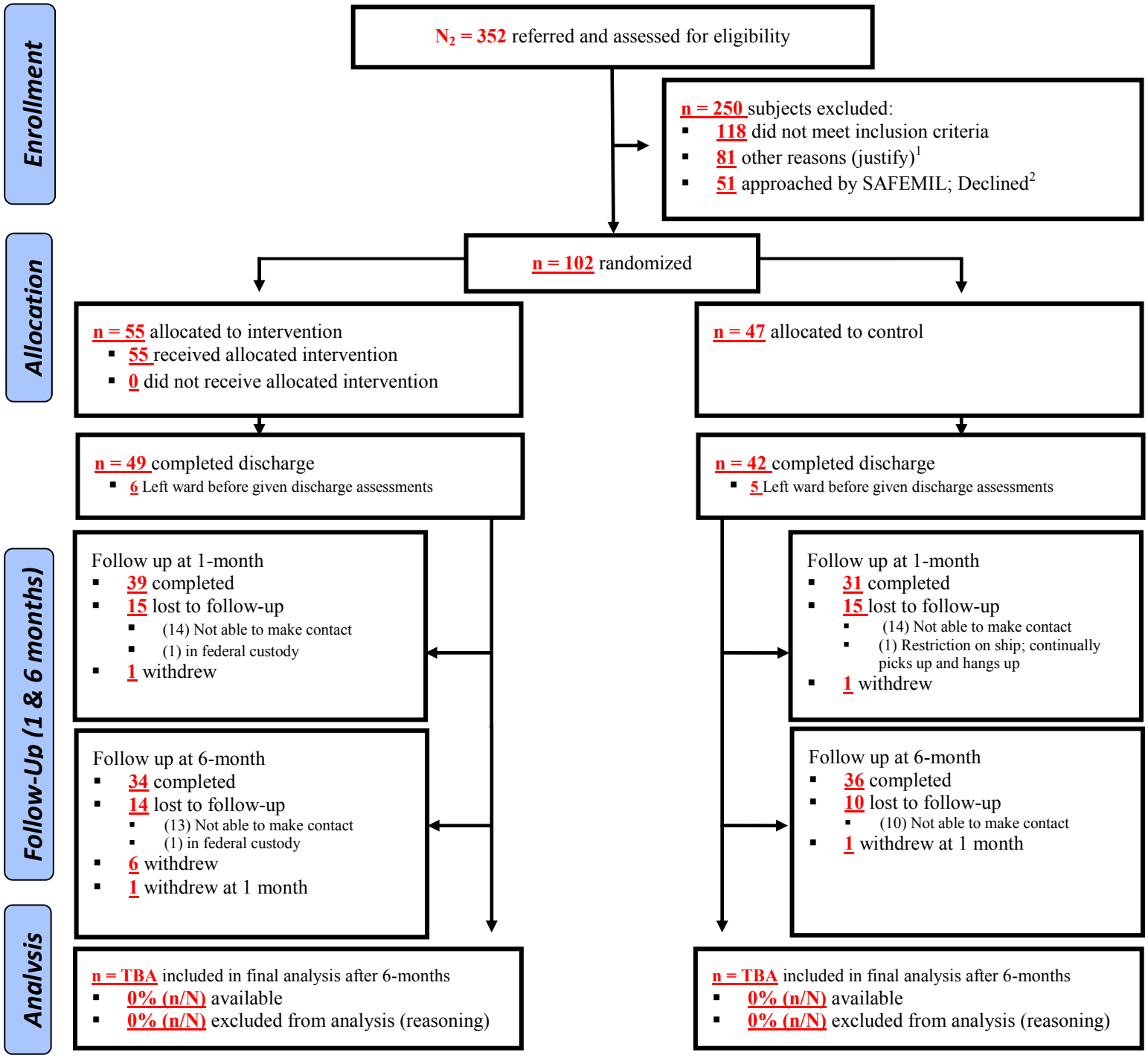
SAFEVET Reasons for Participants Lost to Follow-up

191	Total # of subjects lost to follow-up
78	Withdrawn because did not complete baseline assessment
75	Did not complete 6-month follow-up assessment
14	Subjects withdrew because no longer interested in participating or gave no reason
6	Subjects withdrew because no longer comfortable with study
5	Subjects withdrew because too busy to complete assessments
3	Did not meet entry criteria
2	Subjects deceased
2	Feels that the assessments are too long
2	Claims that the assessment questions are not pertinent to him
1	“Dissatisfied with the VA”
1	“Not helpful bringing up past”
1	“Feeling better”
1	Assessment site ceased operations

SAFEMIL Reasons for Participants Lost to Follow-up

31	Total # of subjects lost to follow-up
22	Not able to make contact
7	Discontinued intervention
1	Withdrew because no longer wants to be in study
1	Withdrawn because participant was imprisoned

Appendix E
SAFEMIL CONSORT Diagram
(since beginning of project)



Appendix F

SAFEMIL Baseline Demographic Data

TABLE 1. Baseline Characteristics of Participants

Demographic and Group	SAFE-MIL (n = 55)		Enhanced Usual Care (n = 47)		All Participants (n = 102)	
	N	%	N	%	N	%
Gender						
Female	17	30.9	16	34.0	33	32.4
Male	38	69.1	31	66.0	69	67.6
Race						
Black / African-American	6	10.9	4	8.5	10	9.8
Hispanic / Latino	5	9.1	3	6.4	8	7.8
White / Caucasian	38	69.1	30	63.8	68	66.7
Other	0	0.0	2	4.3	2	2.0
Mixed	6	10.9	8	17.0	14	13.7
Education						
9th - 12th Grade, No Diploma	1	1.8	0	0.0	1	1.0
HS Diploma or Equivalent	15	27.3	8	17.0	23	22.5
Some College, No Degree	23	41.8	21	44.7	44	43.1
Associate's Degree	5	9.1	7	14.9	12	11.8
Bachelor's Degree	8	14.5	6	12.8	14	13.7
Graduate or Professional Degree	3	5.5	5	10.6	8	7.8
Marital Status						
Never Married	29	52.7	16	34.0	45	44.1
Married	16	29.1	17	36.2	33	32.4
Separated/Divorced/Widowed	9	16.4	13	27.7	22	21.6
Unknown	1	1.8	1	2.1	2	2.0
Employment Status						
Military Full Time	47	85.5	37	78.7	84	82.4
Military Reserves	2	3.6	2	4.3	4	3.9
Non-Military Full Time	2	3.6	0	0.0	2	2.0
Non-Military Part Time	1	1.8	0	0.0	1	1.0
Unemployed	0	0.0	1	2.1	1	1.0
Student	1	1.8	6	12.8	7	6.9
Unknown	2	3.6	1	2.1	3	2.9
Military Branch						
Army - Active Duty	9	16.4	11	23.4	20	19.6
Army - Reserves	1	1.8	3	6.4	4	3.9
Army - National Guard	2	3.6	1	2.1	3	2.9
Air Force - Active Duty	9	16.4	4	8.5	13	12.7
Coast Guard - Active Duty	1	1.8	1	2.1	2	2.0
Marine Corps - Active Duty	11	20.0	3	6.4	14	13.7
Navy - Active Duty	18	32.7	22	46.8	40	39.2
Unknown	4	7.3	2	4.3	6	5.9

Military Deployment						
No	24	43.6	20	42.6	44	43.1
Yes	30	54.5	26	55.3	56	54.9
Unknown	1	1.8	1	2.1	2	2.0
Military Combat						
No	40	72.7	34	72.3	74	72.5
Yes	14	25.5	12	25.5	26	25.5
Unknown	1	1.8	1	2.1	2	2.0
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age (years)	28.55	8.77	30.72	9.61	29.55	9.18